

“Grandfathering” *Cryptosporidium* Data under the LT2 Rule: What Every Utility Should Know

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Abstract

Monitoring for *Cryptosporidium* before implementation of the United States Environmental Protection Agency’s Long Term 2 Enhanced Surface Water Treatment Rule (LT2) provides several benefits that will not be available after formal monitoring begins. The main advantage for public water systems to “grandfather data” is to gain additional time for planning and implementation of treatment changes, should *Cryptosporidium* concentrations warrant treatment modifications in accordance with the LT2. Because *Cryptosporidium* concentrations may fluctuate across years, additional data collected during the period leading up to rule implementation may provide a more representative indication of the *Cryptosporidium* concentrations than the minimum 2 years of monitoring. Monitoring before rule implementation provides an opportunity for utility staff to first conduct practice sampling to familiarize themselves with monitoring activities without the risk of a monitoring or reporting violation. In addition, laboratories are likely to be more available before the rule to accommodate utility preferences for sampling dates than during the rule. Guidelines for generating *Cryptosporidium* data for grandfathering can be found at the Agency’s website (<http://www.epa.gov/safewater/lt2/pwsguide.html>).

Introduction

The United States Environmental Protection Agency (USEPA) proposed the LT2 in the Federal Register on August 11, 2003¹. The LT2 would apply to approximately 14,000 public water systems (PWS) serving 180 million people. The agency has estimated that compliance with this rule will avert thousands of cases of Cryptosporidiosis. Under the LT2, PWSs would conduct source water *Cryptosporidium* monitoring to assess the mean *Cryptosporidium* level in the influent to drinking water plants that treat surface water or groundwater under the direct influence of surface water. The monitoring results would determine a “risk bin classification”, which would dictate what, if any, additional *Cryptosporidium* treatment would be required.

As proposed, PWSs could use previously collected (i.e., grandfathered) *Cryptosporidium* monitoring results to determine their LT2 rule bin classification in lieu of, or in addition to, results generated during the LT2 rule implementation period. Increased time for treatment modifications, more representative estimates of pathogen concentrations, sampling practice, and availability of preferred schedule dates all argue for taking advantage of this option. Grandfathered data would need to be equivalent in both quantity and quality to data that would be collected during LT2 rule implementation. The criteria for using previously collected data were listed at 40 CFR part 141.708 in the proposed LT2 rule¹, and guidelines for meeting the criteria² have been summarized below.

Advantages of Grandfathering *Cryptosporidium* Data

Additional time to implement treatment. The LT2 rule monitoring period for a PWS interested in grandfathering will begin the first sample designated for LT2 rule binning and end with the sample designated as the last as long as a minimum of 2 years of acceptable data have been submitted. The final sample may be collected before the end of the LT2 rule implementation period. Sample results generated after the last sample result in the PWS's data package would be considered outside the PWS's LT2 rule monitoring period and would not need to be submitted to USEPA for LT2 rule binning purposes (however, these results may be subject to reporting requirements under other federal or State regulations). In situations where *Cryptosporidium* monitoring results classify the PWS into an LT2 bin that requires further treatment, grandfathering may provide the PWS with more time to plan for, and implement, the additional treatment.

Estimation of *Cryptosporidium* prevalence. PWSs that begin monitoring before the LT2 rule is implemented have the option of generating more than the minimum 2 years of monitoring data to assess the concentration of *Cryptosporidium* in their influent. Because *Cryptosporidium* concentrations may fluctuate across years, supplementing 2 years of monitoring with additional data collected during the months or years leading up to rule implementation may provide a more representative indication of the *Cryptosporidium* concentrations for calculating a PWS' bin value than the minimum 2 years of monitoring.

For PWSs that collect a total of at least 48 samples, USEPA has proposed that the *Cryptosporidium* bin concentration will be equal to the arithmetic mean of all sample concentrations. For PWSs that serve at least 10,000 people and collect a total of at least 24 samples, but not more than 47 samples, USEPA has proposed that the *Cryptosporidium* bin concentration will be equal to the highest arithmetic mean of all sample concentrations in any 12 consecutive months during which *Cryptosporidium* samples were collected. For PWSs that serve fewer than 10,000 people and monitor for only 1 year, bin classification would be based on the arithmetic mean of all sample concentrations.

Practice samples and laboratory support. PWSs monitoring before rule implementation also have the opportunity to use the first several events as "practice" sample events and provide an opportunity for utility staff to familiarize themselves with monitoring activities without the risk of a monitoring or reporting violation. Laboratory staff can provide guidance and support on specific issues associated with monitoring or shipments to their laboratory, which, based on the experience with the Information Collection Rule, is an important element of success during the first several sampling events.

Sample schedule. Because laboratories must meet sample holding times, and can only process a limited number of samples each day, the increase in analytical demand after rule promulgation could cause saturation of popular sampling dates, where the laboratory cannot accept additional samples during that time period without jeopardizing holding times. If this occurs on the PWS' preferred sampling date(s), then the PWS may need to make adjustments in their plant's schedule to accommodate LT2 rule monitoring.

However, prior to rule promulgation, the workload in *Cryptosporidium* laboratories is expected to be lower, and monitoring during this period, rather than during the formal rule implementation period, provides PWSs with more flexibility in establishing dates. This also will likely be the case where the PWS will monitor both before and during rule implementation, because a PWS that starts monitoring early will have established a schedule with the laboratory before the majority of remaining PWSs prepares for monitoring.

Guidelines for Generating Grandfathered Data

The salient features of the guidelines are outlined below; however, the utility should follow the Agency's guidelines in their entirety (<http://www.epa.gov/safewater/lt2/pwsguide.html>).

Sample collection location. *Cryptosporidium* samples intended for grandfathering under the LT2 rule should be collected from the plant intake prior to any treatment. Plants that do not have a sampling tap located prior to any treatment should: 1) manually collect source water samples as close to the intake as is feasible, at a similar depth and distance from shore; 2) install a new tap prior to treatment; or 3) discontinue chemical addition before sample collection until the plant has verified that the chemical is not detected by the appropriate analytical method.

PWSs with multiple surface water sources and blended surface water and ground water sources should collect their samples from a sampling tap positioned where the sources are combined prior to treatment, if this is available. If this is not available, then samples can be manually collected at each source near the intake on the same day and composited into one sample. The volume of sample from each source should be weighted according to the proportion of that source used by the plant. For example, if a plant has two sources and 75% of the drinking water is from Source A and 25% is from Source B, then for a 10-L sample, 7.5 L would be collected from Source A and combined with 2.5 L collected from Source B. Combined samples should reflect plant operation at the time the sample is collected and may change during the monitoring period. Although this approach requires sample compositing by utility personnel prior to shipment to the laboratory, it results in a single sample, and reduces analytical and shipping costs.

Alternatively, separate samples can be collected at each source near the intake on the same day and analyzed independently. The results would then be used to calculate a weighted average of the analysis results. The weighted average would be calculated by multiplying the analytical result for each source by the fraction of the source contribution to total plant flow at the time the samples were collected, and then summing these values. For example, if a plant has two sources and 75% of the drinking water is from Source A and 25% is from Source B, then one sample would be collected from each source and analyzed independently. If the concentration of oocysts for the sample from Source A was 5 oocysts/L and the concentration of the sample from Source B was 1 oocyst/L, the final result for the plant for this sampling event would be 4 oocysts/L ($[5 \text{ oocysts/L} \times 0.75] + [1 \text{ oocyst/L} \times 0.25]$). This approach eliminates the need for compositing in the field, but results in increased costs for the additional sample.

Monitoring frequency. To generate data that would be eligible for grandfathering, PWSs will need to collect samples at least monthly, and in equal intervals of time over the entire collection period. For example, if a PWS collects samples on a biweekly basis, this biweekly sampling approach needs to be maintained throughout the monitoring period.

Sampling schedule. PWSs should develop a schedule listing the calendar date on which each *Cryptosporidium* sample will be collected and include this schedule when submitting the grandfathered data package to USEPA. PWSs that have already begun monitoring without establishing a sampling schedule should develop a schedule for collecting the remaining samples. PWSs need to collect samples within 2 days before or after the dates indicated in their sampling schedules, with some exceptions for conditions beyond the PWS' control. These include extreme conditions that may pose danger to the sampler, or which are unforeseen or cannot be avoided and which cause the system to be unable to sample in the required time frame. If these situations prevent a grandfathered sample from being collected on schedule, the PWS needs to sample as close to the scheduled date as feasible and submit an explanation for the alternative sampling date with the grandfathered data package. Similarly, if a PWS fails to generate valid *Cryptosporidium* analytical results for a scheduled sampling date due to laboratory problems (such as failure to comply with the analytical method quality control requirements), the PWS should collect a replacement sample within 14 days of being notified by the laboratory that a result cannot be reported for that date. PWSs need to submit an explanation for the alternative sampling date with the grandfathered data package. In all instances, alternative sample collection dates during grandfathered monitoring should be timed so as not to coincide with another scheduled *Cryptosporidium*

sample collection date.

Analytical methods. USEPA Methods 1622 or 1623 for *Cryptosporidium* analyses have been updated several times since the original interlaboratory validation studies were performed (and during which grandfathered data may have been generated). Versions including the 1999, 2001, and 2003 revisions of the methods are all acceptable for grandfathering. Although the 1999 versions of the methods are acceptable for use prior to the release of the 2001 versions, these versions should not have been used after the end of 2001, when laboratories had switched to the updated versions. The method changes in the 2003 versions of the methods largely clarify existing procedures. EPA recommends that PWSs planning to grandfather *Cryptosporidium* data should use the 2003 versions of the methods.

Sample volume. Grandfathered samples must meet the same requirements as those analyzed after the LT2 rule is implemented. This includes laboratory analysis of a minimum of 10 L of sample, 2 mL of packed pellet volume, or as much volume as two filters can accommodate before clogging. This approach is designed to achieve a balance between the need to analyze sufficient volume to adequately characterize source water *Cryptosporidium* concentrations and the desire to not unreasonably burden PWSs with highly turbid water sources with excessive laboratory costs for analysis of large numbers of “subsamples.” (Subsamples represent the maximum volume of sample concentrate that can be purified). USEPA is investigating whether the subsample volume can be increased, which would reduce analytical costs for PWSs, but this determination will not affect the currently specified minimum sample volume requirements.

PWSs are permitted to analyze larger sample volumes and USEPA recommends that PWSs analyze similar sample volumes throughout the monitoring period. However, data sets including different sample volumes would be acceptable under the proposed rule, provided the PWS analyzes at least the minimum sample volume for each sample.

Matrix spike samples. During USEPA’s on-site audits of laboratories applying for approval under the *Cryptosporidium* Laboratory Quality Assurance Program (Lab QA Program), one of the most common problems encountered during review of data is the lack of matrix spike (MS) sample data. PWSs intending to grandfather data need to be sure to collect samples for matrix spike analysis at the required frequency to avoid having the data set rejected. USEPA Method 1622/1623 requires MS samples to be analyzed at a frequency of 1 MS sample for every 20 monitoring samples from each plant. The MS sample and the associated unspiked sample must be analyzed by the same procedure and the MS sample must be the same volume as the associated monitoring sample. While the MS sample results are not expected to not be used to adjust *Cryptosporidium* recoveries at any individual source water; the MS results are expected to be used collectively to assess overall recovery and variability for USEPA Method 1622/1623 in source water. No resampling would be necessary for MS samples that do not meet USEPA Method 1622/1623 recovery guidelines.

***Cryptosporidium* laboratories.** PWSs should ensure that their grandfathered *Cryptosporidium* samples are analyzed by laboratories that have been evaluated and approved under the Lab QA Program before the data are submitted to USEPA. USEPA has established the Lab QA Program to approve laboratories for performing *Cryptosporidium* analyses under the LT2 rule (http://www USEPA.gov/safewater/lt2/cla_final.html).

***E. coli* and turbidity measurements.** The proposed LT2 rule requires that PWSs that provide filtration and serve at least 10,000 people collect *E. coli* and turbidity samples along with *Cryptosporidium* samples when monitoring under the rule. USEPA requests that PWSs conducting grandfathered monitoring collect and analyze *E. coli* samples with each *Cryptosporidium* sample and measure turbidity during each sampling event. However, USEPA does not anticipate excluding the use of previously collected *Cryptosporidium* data if *E. coli* and turbidity samples were not collected.

Reporting grandfathered data. PWSs interested in submitting grandfathered *Cryptosporidium* data may do so after the LT2 rule is finalized. PWSs may continue to monitor during the months between promulgation and implementation of the rule. The approach is designed to accommodate both PWSs that will have complete grandfathered data sets at the time of the rule, and those that intend to use grandfathered data in conjunction with monitoring during the rule.

Conclusion

Monitoring for *Cryptosporidium* before the implementation of the LT2 rule is likely to provide PWSs with a range of benefits that will not be available to systems that monitor after formal monitoring begins. The benefits of grandfathering include: 1) additional time to modify treatment, if pathogen concentrations place the PWS in one of the higher bin categories; 2) a more representative estimate of source water *Cryptosporidium* concentrations; 3) practice with monitoring activities without penalty for mistakes; and 4) establishment of a preferred sampling schedule.

References

1. Environmental Protection Agency. 2003. Federal Register. 40 CFR Parts 141 and 142 National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule; Proposed Rule, August 11, 2003.
2. United States Environmental Protection Agency. 2003. Source Water Monitoring Guidance Manual for Public Water Systems for the Long Term 2 Enhanced Surface Water Treatment Rule (LT2 Rule). Draft June 2003. Available @ <http://www.epa.gov/safewater/lt2/pwsguide.html>

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